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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,888	03/24/2004	David J.S. Kim	P11111.00	5592

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EXAMINER	
LUSTUSKY, SARA	
ART UNIT	**PAPER NUMBER**
3735	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,888	KIM ET AL.	
	Examiner	Art Unit	
	Sara Lustusky	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/05/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The Examiner acknowledges Applicant's Amendment dated February 5, 2007. Claims 1-2, 21, 23, 24 and 26 are amended. Claims 1-36 are pending.

Specification

As set forth in the Office Action dated October 11, 2006, the abstract of the disclosure is objected to because it exceeds the 150 word limit. Correction is required. See MPEP § 608.01(b).Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Drawings

As set forth in the Office Action dated October 11, 2006, the drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: (53) as seen in Figure 4. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37

CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 1 and 3 are objected to because of the following informalities: The recitation "to be used in method of" in line 1 of claim 1 should read - - to be used in a method of - -; the recitation "and selectively operated to" in line 5 of claim 3 should read - - and is selectively operated to - -. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Spence et al. (US 6019722 A).

Spence et al. teaches a method of using a suction-assisted tissue-engaging device to perform a medical procedure on body tissue accessed through an incision into a body cavity, comprising an elongated articulating arm (64) extending between an articulating arm proximal end and an articulating arm distal end enclosing an arm vacuum lumen coupled with a vacuum port (62) for drawing a vacuum (V) through the arm vacuum lumen, the articulating arm (64) adapted to be manipulated in a flexible state into an operative shape and changed into a rigid state maintaining the operative shape (as described in lines 23-35 of column 9 and in lines 26-36 of column 10),

wherein said arm vacuum lumen (as seen in Figure 3) exhibits a vacuum leak (between spherical links 90 and tubular links 92) when the articulating arm (64) is in the flexible state, and wherein the vacuum leak is sealed (by o-ring seals 98) as the articulating arm (64) is changed from the flexible state to the rigid state (as described in lines 23-35 of column 9 and in lines 26-36 of column 10) (as may be seen in Figures 3 and 7A); wherein said vacuum leak is sealed by sealing means (98) as the articulating arm (64) is changed from the flexible state to the rigid state; and a suction member (52, 82, 86) coupled to the articulating arm (64) distal end having a suction member vacuum lumen (through holes 62 and as seen within extension arms 80 in Figure 3) coupled with the arm vacuum lumen extending to at least one suction port (within 82, 86) adapted to be applied against the body organ, whereby vacuum drawn through said vacuum port (62) provides suction at the suction port to engage body tissue; further comprising tensioning means (96) coupled to the elongate articulating arm (64) adapted to be selectively operated to render the articulating arm (64) in the flexible state, enabling manipulation of the articulating arm (64) into the operative shape, wherein the arm vacuum lumen exhibits a vacuum leak (between 90 and 92), and is selectively operated to render the articulating arm (64) in the rigid state maintaining the operative shape imparted to the articulating arm (64); and wherein said sealing means (98) seals the vacuum leak as the tensioning means (96) is operated to change the flexible state to the rigid state (as described in lines 26-36 of column 10), wherein said articulating arm (64) further comprises a plurality of interlocking articulating links (90, 92) each having a link proximal end and a link distal end and a link bore extending between the link proximal and distal ends of adjacent articulating links shaped to provide end to end articulation

with the link bores aligned (as seen in Figure 3); wherein said tensioning means (96) comprises an elongate tensioning cable extending through the articulating link bores between a cable proximal end and a cable distal end proximate the suction member, whereby the aligned link bores provide the arm vacuum lumen alongside the elongated tensioning cable (as seen in Figures 3 and 7A); wherein during use said vacuum is drawn through said vacuum lumen and said suction port engages body tissue, wherein said articulating arm (64) is shaped into an operative shape disposing said suction port against said body tissue and locked into said rigid state.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-20 and 22-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence et al. (US 6019722 A) as applied to claims 3 and 21 above, in view of Boone et al. (US 6464629 B1).

Spence et al. teaches the limitations of claim 3 as described above, wherein said articulating arm (64) comprises a series of articulating links (90, 92) which enable selective flexibility of said articulating arm (64), wherein said tensioning means is coupled to said cable proximal end and is selectively operable to release tension in said tensioning cable (96) to render said articulating arm (64) in a flexible state enabling manipulation of said articulating arm (64) into an operative shape and to impart tension

to said tensioning cable (96) to drawn the link proximal and distal ends together (as describe din lines 26-36 of column 10), wherein said sealing means further comprises a resilient seal having a seal bore and is fitted into a seal seat of an articulating link (90, 92) distal to said tensioning means with the tensioning cable extending through the seal bore (as seen in Figures 7A-B) and the seal is compressed against the tensioning cable and seal seat preventing any vacuum leak proximal to said seal seat when said articulating arm (64) is in the rigid state (as described in lines 26-36 of column 10), wherein said vacuum port (indicated as coming from V) extends from the link bore of an articulating link disposed distal to said seal seat (as seen in Figures 3 and 9), wherein said resilient seal and seal bore are dimensioned with respect to the seal seat and the tensioning cable such that the resilient seal is compressible against the seal seat and the tensioning cable sufficient to reduce said vacuum leak proximal to said seal seat as the tensioning cable is drawn proximally while the articulating arm (64) remains in the flexible state allowing manipulation of the articulating arm (64) into an operative shape as the rigid state is achieved after said tensioning cable (96) is sufficiently tightened and locked into a desired position. However, Spence et al. does not disclose the use of a sheath over said articulating arm (64), nor that said suction member comprises at least two stabilizer pods that may be spread apart.

Boone et al. teaches a tissue engaging device comprising an articulating arm (20) comprising articulating links (120), a suction member (22) connected at a distal end of said articulating arm (20), and a tensioning cable used as a tensioning means to create a rigid state within said articulating arm (20) by forcing said articulating links (120) together (as described in lines 45-65 of column 5), wherein said tissue engaging

device comprises an elongate flexible outer sheath having an outer sheath lumen extending between an outer sheath distal end coupled to said suction member and an outer sheath (27) proximal end coupled to said articulating arm proximal end (as described in lines 42-49 of column 6) (as seen in Figure 2), wherein said suction member (22) comprises a suction member sub-assembly comprising first and second distally extending stabilizer pods (22) each having at least one suction port adapted to be applied against body tissue and coupled to the suction member vacuum lumen, wherein said stabilizer pods (22) comprise a suction pad diverging into a plurality of flexible appendages (as seen in Figure 1F at locations 32, 33 and seen in Figures 33-37), each having at least one suction port coupled to the suction member vacuum lumen and shaped to conform anatomically to an area of a body organ to enable the body organ to be moved into and maintained in a non-physiologic position within the body cavity (as described in lines 38-60 of column 12), and spreading means operable when suction is applied through the suction ports to the body tissue and responsive to tension imparted to the tensioning cable to render the articulating arm in the rigid state for spreading the stabilizer pods (22) apart to stretch the body tissue between the first and second suction pods (as described in the abstract and in lines 35-45 of column 3, in lines 18-48 of column 6 and from line 55 of column 8 through line 2 of column 9), wherein said spreading means include a cable (40) which runs through the entire length of said articulating arm to said suction member sub assembly (as described from line 57 of column 9 through line 3 of column 10), wherein said stabilizer pods (22) are spread apart when suction is applied through the suction ports to the body tissue during a medical procedure.

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine a sheath similar to that of Boone et al. with a device similar to that of Spence et al. in order to protect the body and the surgical site from the articulating links in view of the teachings of Boone et al. (as described in lines 44-45 of column 6 of Boone et al.). It would have been further obvious to one having ordinary skill in the art at the time of the invention to combine a suction member similar to that of Boone et al. with an articulating arm similar to that of Spence et al. in order to eliminate the need for separate vacuum lines running from a vacuum source to a suction member thereby reducing manufacturing costs and potential assembly complications.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (US 2002/0099268 A1) in view of Spence et al. (US 6019722 A).

Paul et al. teaches a suction-assisted tissue-engaging device and method of using comprising:

a. an elongated articulating arm (30) extending between an articulating arm proximal end and an articulating arm distal end enclosing an arm vacuum lumen (710) coupled with a vacuum port where the vacuum source is attached to the distal portion of the vacuum lumens (710 or 770) (as seen in Figure 15A), the articulating arm (30) adapted to be manipulated in a flexible state into an operative shape and changed into a rigid state maintaining the operative shape (as described in paragraph [0014]);

b. a suction member (20, 600) coupled to the articulating arm distal end having a suction member vacuum lumen (618, 708) coupled with the arm vacuum lumen (710) extending to at least one suction port (632) adapted to be

applied against the body organ (as seen in the embodiments in Figures 14A-G and 15A-B) (as described in paragraphs [0024]-[0025]; in paragraphs [0099]-[0100]);

c. an elongated flexible outer sheath (460, 760) having a lumen (as described in lines 29-36 of column 4) extending between an outer sheath distal end coupled to the suction member (20, 600) and an outer sheath proximal end coupled to the articulating arm proximal end (as seen in the embodiments in Figures 10F and 15A) (as described in paragraph [0141]);

d. a plurality of interlocking articulating links within the outer sheath lumen, the links each having a proximal end and distal end and a link bore and an elongated tensioning cable extending through the articulating link bores(770), whereby the aligned link bores provide the arm vacuum lumen (710 or 770) alongside the elongated tensioning cable (288) (as seen in Figures 4 and 15A) (as described in paragraph [0111]);

e. tensioning means coupled to the cable proximal end that is selectively operable to release tension in the cable and to impart tension in the cable to manipulate the links produce a flexible and rigid state in the articulating arm (as described in paragraph [0014]); and

f. wherein the suction member (600) further comprises a suction pad diverging into a plurality of flexible appendages (602, 604) each having at least one suction port (608, 610) coupled to the suction member vacuum lumen (at 616, 618) and adapted to be applied against body tissue and shaped to conform

to an area of a body organ (as seen in Figures 14A-G), and able to move an organ into a non-physiological position;

g. wherein the distal suction member further comprises: a suction member sub-assembly coupled to the cable distal end incorporating the suction member vacuum lumen coupled with the arm vacuum lumen and supporting first and second suction pods to extend distally substantially in parallel and spaced apart from one another each having at least one suction port coupled to the suction member vacuum lumen (as seen in Figures 14A-15B); and

h. a suction member outer sealing sleeve extending over at least a portion of the suction member sub-assembly sealing the suction member vacuum lumen from vacuum leakage (as seen in Figure 15A).

However, Paul et al. does not teach an articulating arm that exhibits a vacuum leak from the arm vacuum lumen when in a flexible state and wherein the vacuum leak is sealed by changing the articulating arm into a sealed state.

Spence et al. teaches a method of using a suction-assisted tissue-engaging device to perform a medical procedure on body tissue accessed through an incision into a body cavity, as described above, wherein said arm vacuum lumen (as seen in Figure 3) exhibits a vacuum leak (between spherical links 90 and tubular links 92) when the articulating arm (64) is in the flexible state, and wherein the vacuum leak is sealed (by o-ring seals 98) as the articulating arm (64) is changed from the flexible state to the rigid state (as described in lines 23-35 of column 9 and in lines 26-36 of column 10) (as may be seen in Figures 3 and 7A).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine an articulating arm having an internal vacuum lumen similar to that of Spence et al. with a device similar to that of Paul et al. in order to eliminate the need for separate vacuum lines running from a vacuum source to a suction member thereby reducing manufacturing costs and potential assembly complications.

Response to Arguments

Applicant's arguments, see Applicant's Amendment, filed February 5, 2007, with respect to the rejection(s) of claim(s) 1, 10-11 13, 16, 18-21, 25 and 30 under 35 USC 102 in the Office Action dated October 11, 2006 have been fully considered and are persuasive in view of Applicant's amendments to the claims. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Paul et al. (US 2002/0099268 A1), Spence et al. (US 6019722 A) and Boone et al. (US 6464629 B1). In view of the new ground(s) of rejection, the indication of allowable subject matter set forth in the Office Action dated October 11, 2006 are also withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.L.

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